Who should not take ZOLOFT?

Do not take ZOLOFT if you:

- take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- have taken an MAOI within 2 weeks of stopping ZOLOFT unless directed to do so by your healthcare provider.
- have stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.
- take any other medicines that contain sertraline (such as sertraline HCl or sertraline hydrochloride).
- take the antipsychotic medicine pimozide (Orap®) because this can cause serious heart problems.
- are allergic to sertraline or any of the ingredients in ZOLOFT. See the end of this Medication Guide for a complete list of ingredients in ZOLOFT.
- take Antabuse® (disulfiram) (if you are taking the liquid form of ZOLOFT) due to the alcohol content.

People who take ZOLOFT close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- rapid changes in heart rate or blood pressure
- uncontrolled muscle spasms
- confusion
- stiff muscles
- loss of consciousness (pass out)

What should I tell my healthcare provider before taking ZOLOFT?

Before starting ZOLOFT, tell your healthcare provider:

- **if you have:**
  - liver problems
  - heart problems
  - bipolar disorder or mania
  - kidney problems.
  - or have had seizures or convulsions
  - low sodium levels in your blood
  - a history of a stroke
  - high blood pressure
  - or have had bleeding problems
- **are pregnant or plan to become pregnant.** Your baby may have withdrawal symptoms after birth or may be at increased risk for a serious lung problem at birth. Talk to your healthcare provider about the benefits and risks of taking ZOLOFT during pregnancy.
- **are breastfeeding or plan to breastfeed.** A small amount of ZOLOFT may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking ZOLOFT.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ZOLOFT and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take ZOLOFT with your other medicines. **Do not** start or stop any medicine while taking ZOLOFT without talking to your healthcare provider first.

How should I take ZOLOFT?

- Take ZOLOFT exactly as prescribed. Your healthcare provider may need to change the dose of ZOLOFT until it is the right dose for you.
- ZOLOFT Tablets may be taken with or without food.
- ZOLOFT Oral Solution may look cloudy or hazy after mixing, this is normal.
- ZOLOFT Oral Solution must be diluted before use:
  - **Do not** mix ZOLOFT until you are ready to take it.
  - When diluting ZOLOFT Oral Solution, use **only** water, ginger ale, lemon/lime soda, lemonade, or orange juice.
  - The oral dropper contains latex. If you are sensitive or allergic to latex, ask your healthcare provider or pharmacist about the best way to measure your medicine.
- If you miss a dose of ZOLOFT, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. **Do not** take two doses of ZOLOFT at the same time.

If you take too much ZOLOFT, call your healthcare provider or poison control center right away, or go to the nearest hospital emergency room right away.

What should I avoid while taking ZOLOFT?

ZOLOFT can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how ZOLOFT affects you. **Do not** drink alcohol while you take ZOLOFT.

What are the possible side effects of ZOLOFT?

ZOLOFT may cause serious side effects, including:

- **See "What is the most important information I should know about ZOLOFT?"**

The most common side effects in adults who take ZOLOFT include:

- nausea, loss of appetite, diarrhea, or indigestion
- increased sweating
- tremor or shaking
- agitation
- change in sleep habits including increased sleepiness or insomnia
- sexual problems including decreased libido and ejaculation failure
- feeling tired or fatigued
- anxiety

The most common side effects in children and adolescents who take include abnormal increase in muscle movement or agitation, nose bleeds, urinary incontinence, aggressive reaction, possible slowed growth rate, and weight change. Your child's height and weight should be monitored during treatment with ZOLOFT.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ZOLOFT. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store ZOLOFT?

- Store ZOLOFT at room temperature, 68°F to 77°F (20°C to 25°C).
- Keep ZOLOFT bottle closed tightly.

Keep ZOLOFT and all medicines out of the reach of children.

General information about the safe and effective use of ZOLOFT

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZOLOFT for a condition for which it was not prescribed. Do not give ZOLOFT to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about ZOLOFT. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about ZOLOFT that is written for healthcare professionals.

For more information about ZOLOFT call 1-877-446-3679 (1-877-4-INFO-RX) or go to www.zoloft.com

What are the ingredients in ZOLOFT?

Active ingredient: sertraline hydrochloride

Inactive ingredients:

Tablets: dibasic calcium phosphate dihydrate, D&C Yellow #10 aluminum lake (in 25 mg tablet), FD&C Blue #1 aluminum lake (in 25 mg tablet), FD&C Red #40 aluminum lake (in 25 mg tablet), FD&C Blue #2 aluminum lake (in 50 mg tablet), hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sodium starch glycolate, synthetic yellow iron oxide (in 100 mg tablet), and titanium dioxide.

Oral solution: glycerin, alcohol (12%), menthol, butylated hydroxytoluene (BHT)

This Medication Guide has been approved by the U.S. Food and Drug Administration Revised: 1/2023

Distributed by:
Viatris Specialty LLC
Morgantown, WV 26505 U.S.A.

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Message ID: 17516884-3359

MEDICATION GUIDE

ZOLOFT (ZOH-loft)
(sertraline hydrochloride)
Tablets and Oral Solution

What is the most important information I should know about ZOLOFT?

ZOLOFT and other antidepressant medicines may cause serious side effects. Call your healthcare provider right away if you have any of the following symptoms, or call 911 if there is an emergency.

1. **Suicidal thoughts or actions:**
   - **ZOLOFT and other antidepressant medicines may increase suicidal thoughts or actions** in some people 24 years of age and younger, especially within the **first few months of treatment or when the dose is changed.**
   - Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
   - Watch for these changes and call your healthcare provider right away if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
     - Pay particular attention to such changes when ZOLOFT is started or when the dose is changed.
     - Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

   Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

   - attempts to commit suicide
   - acting aggressive or violent
   - new or worse depression
   - feeling agitated, restless, angry or irritable
   - an increase in activity or talking more than what is normal for you
   - acting on dangerous impulses
   - thoughts about suicide or dying
   - new or worse anxiety or panic attacks
   - trouble sleeping
   - other unusual changes in behavior or mood

2. **Serotonin Syndrome.** This condition can be life-threatening and symptoms may include:
   - agitation, hallucinations, coma, or other changes in mental status
   - racing heartbeat, high or low blood pressure
   - coordination problems or muscle twitching (overactive reflexes)
   - nausea, vomiting, or diarrhea
   - sweating or fever
   - muscle rigidity
3. **Increased chance of bleeding**: ZOLOFT and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin®, Jantoven®), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.
4. **Manic episodes.** Symptoms may include:
   - greatly increased energy
   - racing thoughts
   - unusually grand ideas
   - severe trouble sleeping
   - reckless behavior
   - excessive happiness or irritability
   - talking more or faster than usual
5. **Seizures or convulsions.**
6. **Glaucoma (angle-closure glaucoma).** Many antidepressant medicines including ZOLOFT may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have eye pain, changes in your vision, or swelling or redness in or around the eye. Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
7. **Changes in appetite or weight.** Children and adolescents should have height and weight monitored during treatment.
8. **Low salt (sodium) levels in the blood.** Elderly people may be at greater risk for this. Symptoms may include:
   - Headache
   - weakness or feeling unsteady
   - confusion, problems concentrating or thinking, memory problems
9. **Sexual problems (dysfunction).** Taking selective serotonin reuptake inhibitors (SSRIs), including ZOLOFT, may cause sexual problems.

   Symptoms in males may include:
   - Delayed ejaculation or inability to have an ejaculation
   - Decreased sex drive
   - Problems getting or keeping an erection

   Symptoms in females may include:
   - Decreased sex drive
   - Delayed orgasm or inability to have an orgasm

   Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with ZOLOFT. There may be treatments your healthcare provider can suggest.

Do not stop ZOLOFT without first talking to your healthcare provider. Stopping ZOLOFT too quickly may cause serious symptoms including:
- anxiety, irritability, high or low mood, feeling restless or changes in sleep habits
- headache, sweating, nausea, dizziness
- electric shock-like sensations, shaking, confusion

What is ZOLOFT?

ZOLOFT is a prescription medicine used to treat:
- Major Depressive Disorder (MDD)
- Panic Disorder
- Social Anxiety Disorder
- Obsessive Compulsive Disorder (OCD)
- Posttraumatic Stress Disorder (PTSD)
- Premenstrual Dysphoric Disorder (PMDD)

It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

ZOLOFT is safe and effective in treating children with OCD age 6 to 17 years.

It is not known if ZOLOFT is safe and effective for use in children under 6 years of age with OCD or children with other behavior health conditions.

Talk to your healthcare provider if you do not think that your condition is getting better with ZOLOFT treatment.